

01 - 29 - 07

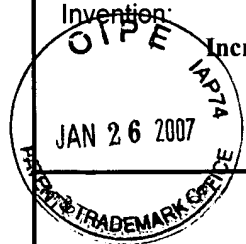
ASB
EFW

TRANSMITTAL OF APPEAL BRIEF (Large Entity)	Docket No. 12.023011 CIP
---	------------------------------------

In Re Application Of: **Hung**

Application No. 10/825,752	Filing Date 04/16/04	Examiner Brown, Michael	Customer No. 38732	Group Art Unit 3734	Confirmation No. 8506
--------------------------------------	--------------------------------	-----------------------------------	------------------------------	-------------------------------	---------------------------------

Invention: **Increasing Retrievable Cells from a Breast Duct**



COMMISSIONER FOR PATENTS:

Transmitted herewith is the Appeal Brief in this application, with respect to the Notice of Appeal filed on:
10/26/06

The fee for filing this Appeal Brief is: **\$500.00**

- ☐ A check in the amount of the fee is enclosed.
- ☐ The Director has already been authorized to charge fees in this application to a Deposit Account.
- ☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 502855. I have enclosed a duplicate copy of this sheet.
- ☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Signature

Dated: 1/26/2007

Theodore Allen
Registration No. 41578
Cytoc Corporation
250 Campus Drive'
Marlborough, MA 01752
Tel: 508-263-8490
Fax: 508-263-2959

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on
_____ (Date)
_____ Signature of Person Mailing Correspondence
_____ Typed or Printed Name of Person Mailing Correspondence

CC:

Attorney's Docket No. 12.023011-CIP

PATENT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Hung et al.

Appl. No.: 10/825,752

Group Art Unit: 3764

Filed: April 16, 2004

Examiner: Michael Brown

For: **INCREASING RETRIEVABLE CELLS FROM A BREAST DUCT**

January 26, 2007

APPEAL BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" filed October 26, 2006.

01/29/2007 SSITHIB1 00000102 502855 10825752

01 FC:1402 500.00 DA

CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)Applicant(s): **Hung**

Docket No.

12.023011 CIP

Application No.

10/825,752

Filing Date

04/16/04

Examiner

Brown, Michael

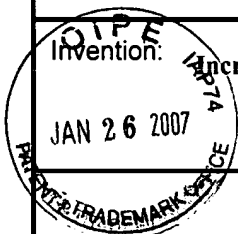
Customer No.

0000 38732

Group Art Unit

3734

Invention:

Increasing Retrievable Cells from a Breast Duct**JAN 26 2007**

I hereby certify that the following correspondence:

Appeal Brief and Transmittal of Appeal Brief (in duplicate)*(Identify type of correspondence)*

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

1-26-07*(Date)***Darry Pattinson***(Typed or Printed Name of Person Mailing Correspondence)**(Signature of Person Mailing Correspondence)***EV 852600165 US***("Express Mail" Mailing Label Number)***Note: Each paper must have its own certificate of mailing.**

Real Party in Interest.

The real party in interest in this appeal is Cytoc Corporation, Inc., the assignee of the above-referenced patent application.

Related Appeals and Interferences.

There are no related appeals and/or interferences involving this application or its subject matter.

Status of Claims.

Claims 1-5 are the subject of this appeal. Claims 1 and 3 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of U.S. Patent No. 6,391,026. Claims 1 and 3 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,255,327. Claims 1 and 2 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,765,403. Claims 1-5 have been rejected under 35 U.S.C. 103(a) as being unpatentable over 6,413,228 U.S. Patent No. in view of U.S. Patent No. 5,255,327. The claims appear in Appendix A. No other claims are pending. No claims have been cancelled.

Status of Amendments.

All of Appellant's amendments have been entered.

Summary of the Claimed Subject Matter.

The pending claims of the present invention are directed to a method for increasing the retrievable cell amount in a breast duct by applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct. A summary of the invention may be found at page 11, lines 13 to 29 of the specification.

Grounds of Rejection to be Reviewed on Appeal.

Issue 1--Whether claims 1 and 2 are patentable under 35 U.S.C. § 102(b) over U.S. Patent No. 5,255,327.

Issue 2--Whether claims 1 and 2 are patentable under 35 U.S.C. 102(b) over U.S. Patent No. 3,765,403.

Issue 3--Whether claims 1-5 are patentable under 35 U.S.C. 103(a) over U.S. Patent No. 6,413,228 in view of U.S. Patent No. 5,255,327.

Issue 4--Whether claims 1 and 3 are patentable under the doctrine of obviousness-type double patenting in view of claim 26 of U.S. Patent No. 6,391,026.

Argument

Issue 1- Whether claims 1 and 3 are patentable under 35 U.S.C. § 102(b) over U.S.

Patent No. 5,255,327 to Endo.

The Examiner has rejected Appellant's claims 1 and 3 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,255,327 to Endo.

The original rejection of claims 1 and 3 under 35 U.S.C. 102(b) was made in the first Office Action of March 21, 2006. In the March Office Action, the Examiner stated that

“Claim 1 and 3 of the present invention only positively recite a method of treating a breast comprising applying vibration to the duct (where ‘to the duct’ can be external to the breast). The ‘increasing a retrievable cell amount’ by ‘inducing cell sloughing’ is an inherent result of the vibration applied to the breast. According to the specification of the present invention, there doesn't appear to be any specific vibrational frequency or specific application method needed to achieve the desired result. In fact, the specification recites on page 12, lines 19-19, the method can also comprise applying vibration or other motion or movement internally or externally to the breast by device, not limited to, ultrasound and other sonic devices.

Since claim 1 can be interpreted very broadly, the Endo vibration device when applied to the breast (col. 2, lines 67-68) would inherently provide the desired result of the method claim (even if very limited).” (page 3; paragraphs 2 and 3)

In the Response to the Office Action of March 21, 2006 dated June 20, 2006, the Appellants argued that there is no teaching or suggestion in Endo of a method of applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and then collecting the sloughed cells from the breast duct. Since Endo makes no mention of collecting cells from a breast duct, Endo cannot anticipate Claim 1. Since Claim 3 contains all of the limitations of Claim 1, Endo therefore cannot anticipate Claim 3.

In the Office Action mailed August 29, 2006, the Examiner argued that “...Endo discloses

inserting a vibrating device into a breast duct. Any vibration into a breast duct would inherently allow cell sloughing. The mere fact that vibration is applied to the duct would cause tissue to adhere to the device inserted into the breast duct.” (page 5 last paragraph to page 6 first paragraph). The Appellants respectfully disagree.

Claim 1 of the present invention recites a method for increasing a retrievable cell amount in a breast duct comprising the steps of applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and collecting the sloughed cells from the breast duct. To establish a case of *prima facie* anticipation, the single reference cited by the Examiner must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention. (Crown Operations Int, Ltd. V. Solutia Inc., 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed Cir. 1984)).

There is no teaching or suggestion in Endo of a method of applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and then collecting the sloughed cells from the breast duct. Endo merely describes a vibrostimulative device that may be attached to a bed or chair to vibrate the whole body or relatively large body area such as hands feet breast or belly. (column 2; lines 60-68). The statement by the Examiner that Endo discloses inserting a vibrating device into a breast duct is not supported by the evidence. Even assuming *arguendo* that the device of Endo could somehow be configured to fit inside a breast duct; there is still no teaching or suggestion in Endo of applying vibration to a breast duct sufficient to induce cell

sloughing within the breast duct. The Examiner's answer that any vibration of a breast would inherently allow cell sloughing in a breast duct is mere supposition by the Examiner without any evidence supporting such a supposition. The Appellants would argue that it is unlikely that all vibrations of the breast will be sufficient to induce cell sloughing within a breast duct.

Lastly, as argued by the Appellants in the response filed June 20, 2006, Endo does not teach or suggest the collecting of sloughed cells from the breast duct. The Examiner argued that the mere fact that vibration is applied to the duct would cause tissue to adhere to the device inserted into the breast duct. Ignoring that fact that Endo does not teach or suggest a device that could be inserted into a breast duct, the argument that any vibration applied to the duct would cause tissue to adhere to the device is again mere supposition by the Examiner without any evidence supporting such a supposition.

The Appellants respectfully submit that the Examiner has not established a case of *prima facie* anticipation because the single reference cited by the Examiner does not describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the invention already existed in the prior art.

. In view of the foregoing, the rejection of claim 1 and 3 under 35 USC 102(b) should be reversed.

Issue 2- Whether claims 1 and 2 are patentable under 35 U.S.C. § 102(b) over U.S. Patent No. 3,765,403 to Brenden.

The Examiner has rejected Appellant's claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,765,403 to Brenden.

The original rejection of claims 1 and 2 under 35 U.S.C. 102(b) was made in the first Office Action of March 21, 2006. In the March Office Action, the Examiner stated that "Similar to Endo above, Brenden discloses an ultrasound device that meets the limitation of the claims since Brenden discloses an ultrasonic vibration to the breast." (page 4; first paragraph)

In the Response to the Office Action of March 21, 2006 dated June 20, 2006, the Appellants argued that since Brenden makes no mention of collecting cells from a breast duct, Brenden cannot anticipate Claim 1. Since Claim 2 contains all of the limitations of Claim 1, Brenden therefore cannot anticipate Claim 2 either.

In the Office Action mailed August 29, 2006, the Examiner argued that "...any method step of inserting a vibration device into a breast duct would inherently cause cell sloughing." (page 6; first paragraph). The Appellants respectfully disagrees.

As mentioned previously, to establish a case of prima facie anticipation, the single reference cited by the Examiner must describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the

field of the invention. (Crown Operations Int, Ltd. V. Solutia Inc., 289 F.3d 1367, 1375, 62 USPQ2d 1917, 1921 (Fed Cir. 1984)).

There is no teaching or suggestion in Brenden of a method of applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and then collecting the sloughed cells from the breast duct. Brenden merely describes an ultrasonic imaging system. (abstract). The statement by the Examiner that Brenden discloses the use of an ultrasonic vibration device on a breast duct to induce cell sloughing within the breast duct is not supported by the evidence. Even assuming *arguendo* that the device of Endo could somehow to be configured to induce cell sloughing within a breast duct; there is still no teaching or suggestion in Brenden to collect sloughed cells from the breast duct. Without a description of collecting cells from a breast duct, Brenden cannot anticipate claims 1 and 2 of the present invention.

The Appellants respectfully submit that the Examiner has not established a case of *prima facie* anticipation because the single reference cited by the Examiner does not describe and enable the claimed invention, including all claim limitations, with sufficient clarity and detail to establish that the invention already existed in the prior art.

In view of the foregoing, the rejection of claim 1 and 2 under 35 USC 102(b) should be reversed.

Issue 3- Whether claims 1-5 are patentable under 35 U.S.C. 103(a) over U.S. Patent No. 6,413,228 to Hung in view of U.S. Patent No. 5,255,327 to Endo.

Claim 1

The Examiner has rejected Appellant's claim 1 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,413,228 to Hung in view of U.S. Patent No. 5,255,327 to Endo. The Appellants respectfully disagree that claim 1 is rendered obvious by Hung in view of Endo. The Examiner has failed to establish a *prima facie* case of obviousness, since Hung and Endo, either alone or in combination, fail to provide the necessary motivation or expectation of success for the ordinarily skilled artisan to arrive at the claimed invention.

To establish a *prima facie* case of obviousness, it is necessary for the Examiner to present evidence, preferably in the form of some teaching, suggestion, incentive or inference in the applied references, or in the form of generally available knowledge, that one having ordinary skill in the art would have been motivated to make the claimed invention. See, e.g., *Carella v. Starlight Archery*, 804 F.2d 135, 231 USPQ 644 (Fed. Cir. 1986); and *Ashland Oil, Inc. v. Delta Resins and Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985).

A new combination of elements can be patented "whether it be composed of elements all new, partly new or all old." *Rosmount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1546, 221 USPQ 1, 7 (CAFC 1984). The Court of Appeals for the Federal Circuit has forcefully stated that a claim rejection must provide a specific motivation in the art for combining elements from cited art in order to establish obviousness of a new combination.

“[C]ase law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. ... Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor’s disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. ... [Evidence of a suggestion, teaching, or motivation to combine] must be clear and particular. ... Broad conclusory statements regarding the teaching of multiple references, standing alone, are not ‘evidence.’ ... [A] reference-by-reference, limitation-by-limitation analysis fails to demonstrate how the [cited] references teach or suggest their combination ... to yield the claimed invention,” and a conclusion of obviousness based on such an analysis “as a matter of law, cannot stand.” *In re Dembiczak*, 175 F.3d 994, 999, 1000, 50 USPQ2d 1614, 1617, 1618 (Fed. Cir. 1999), emphasis added.

Dembiczak involved patent claims to “a large trash bag made of orange plastic and decorated with lines and facial features, allowing the bag, when filled with trash or leaves, to resemble a Halloween-style pumpkin, or jack-o'-lantern.” *Dembiczak*, 996, 1616. The prior art cited by the Board included: a book describing how to teach children to make a "Crepe Paper Jack-O-Lantern;" a book describing a method of making a "paper bag pumpkin" by stuffing a bag with newspapers, painting it orange, and then painting on facial features with black paint; a U.S. Patent describing a bag apparatus wherein the bag closure is accomplished by the use of folds or gussets in the bag material; design patents issued to *Dembiczak*; and prior art "conventional" plastic lawn or trash bags. The Federal Circuit held that the claimed pumpkin-style trash bag was not obvious because there was no clear, particular motivation to combine the cited references.

This holding of *Dembiczak* that evidence of motivation to combine must be clear and particular to establish obviousness has been emphasized over and over again by the Federal

Circuit since *Dembiczak* was decided. It was strongly reemphasized in *Ruiz v. A.B. Chance Co.*,
57 USPQ2d 1161 (Fed. Cir. 2000):

In order to prevent a hindsight-based obviousness analysis, we have clearly established that the relevant inquiry for determining the scope and content of the prior art is whether there is a reason, suggestion, or motivation in the prior art or elsewhere that would have led one of ordinary skill in the art to combine the references. See, e.g., *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("[T]he Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious."); *In re Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617 ("Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references."). "Determining whether there is a suggestion or motivation to modify a prior art reference is one aspect of determining the scope and content of the prior art, a fact question subsidiary to the ultimate conclusion of obviousness." *Sibia Neurosciences, Inc. v. Cadus Pharma. Corp.*, 225 F.3d 1349, 1356, 55 USPQ2d 1927, 1931 (Fed. Cir. 2000); *Tec Air, Inc. v. Denso Mfg., Inc.*, 192 F.3d 1353, 1359, 52 USPQ2d 1294, 1298 (Fed. Cir. 1999) (stating that the factual underpinnings of obviousness include whether a reference provides a motivation to combine its teachings with those of another reference).

... there is "a general rule that combination claims can consist of combinations of old elements as well as new elements," *Clearstream Wastewater Sys. v. Hydro-Action, Inc.*, 206 F.3d 1440, 1446, 54 USPQ2d 1185, 1189-90 (Fed. Cir. 2000), "[t]he notion . . . that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, § 103." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1575, 1 USPQ2d 1593, 1603 (Fed. Cir. 1987); *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed. Cir. 1997) ("It is insufficient to establish obviousness that the separate elements of the invention existed in the prior art, absent some teaching or suggestion, in the prior art, to combine the elements."). *Ruiz* at 1167

Applying this standard to the references cited by the Examiner, it is clear that the Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to

impel a person of ordinary skill in the art to combine the teachings in the applied references in the proposed manner to arrive at the invention of claim 1. The motivation cited in the Office Action for the proposed combination is as follows:

“...Hung was used to set forth the environment of a method of massaging a breast, which of course would include a breast duct. Endo was used as a modifier to substitute vibration for massaging. As set forth in the rejections, fast massaging provides a form of vibration.”

(see August 29, 2006 Office Action; page 6, first paragraph).

This statement does not provide the clear, particular suggestion in the art for making the specific claimed combination as is required. The Examiner has failed to meet the burden of providing evidence of a motivating force sufficient to impel a person of ordinary skill in the art to use a method for increasing a retrievable cell amount in a breast duct by applying vibration to a breast duct sufficient to induce cell sloughing within the breast duct and collecting the sloughed cells from the breast duct wherein applying vibration to the breast duct increases the retrievable amount of cells collected from the breast duct as described in claim 1.

Hung does not teach or suggest the use of vibration to increase the retrievable amount of cells collected from a breast duct. The deficiency of Hung cannot be made up by Endo. The assertion by the Examiner that rapid massaging is equivalent to vibration is not supported by any evidence. One of skill in the art would not have looked to Endo to teach that vibrational energy could be applied to breast ducts to increase the retrievable amount of cells collected since Endo makes no mention of applying vibration to breast ducts. The force exerted by a massage is very

different than the force exerted by vibration. While massage may be able to manipulate breast ducts close to the surface of the breast, vibration such as ultrasound can penetrate deep into the breast tissue to reach those ducts which would not be accessible through massage. The Appellant would point out that claim 1 recites a method for applying vibration to a breast duct to increase the retrievable amount of cells collected from the breast duct. Since vibration can reach breast ducts not accessible by massage, the application of vibration to breast duct in order to specifically increase cell sloughing would be a non-obvious improvement over previous methods of increasing the cellular content collected from breast ducts.

The obviousness rejection is based on hindsight from these disparate references to provide random elements of the claims. There is no clear, particular motivation in the references to reach the claimed invention.

Thus, a *prima facie* case of obviousness has not been established because the Examiner has not presented evidence that one having ordinary skill in the art would have been motivated to combine Hung and Endo to make the claimed invention. In view of the foregoing, the rejection of claim 1 under U.S.C. § 103(a), should be reversed.

Claims 2-5

The Examiner rejected dependent claim 2-5 under 35 U.S.C. § 103(a) over U.S. Patent No. 6,413,228 to Hung in view of U.S. Patent No. 5,255,327 to Endo. The Appellant disagrees that claims 2-5 are rendered obvious by Hung in view of Endo.

To establish a *prima facie* case of obviousness includes the criteria that all of the

limitations of the claims must be taught or suggested by the prior art. *In re Royka* 490 F.2d 981 (C.C.P.A. 1974). Since, under the obviousness standard, the prior art must teach or suggest all the limitations of the claims, then it is axiomatic that non-enabling disclosures should not be considered prior art (See *e.g.*, *In re Wilder*, 429 F.2d 447, 166 USPQ 545, 548 (C.C.P.A. 1970)).

Dependent claim 2 limits the scope of the vibration to ultrasound. Neither Hung nor Endo teach or suggest the use of ultrasound sufficient to induce cell sloughing within a breast duct. Dependent claim 3 has the limitation of applying vibration to a breast duct either externally or internally. Neither Hung nor Endo teach or suggest the use of applying vibration either externally or internally in order to increase the retrievable amount of cells collected from the breast duct. Dependent claim 4 has the limitation of the use of vibration combined with heat and/or massage. Neither Hung nor Endo teach or suggest the use of applying heat and vibration in order to increase the retrievable amount of cells collected from the breast duct. Dependent claim 5 has the limitation of collecting a retrievable cell amount is collected through ductal lavage. Although Hung describes the use of ductal lavage to collect fluid infused into breast duct (ductal lavage, neither Hung nor Endo teach or suggest the use of applying vibration either externally or internally in order to increase the retrievable amount of cells collected from the breast duct.

The Examiner has not pointed to any teaching or suggestion within Hung nor Endo to anticipate these limitations. The Examiner has failed to establish a *prima facie* case of obviousness, since Hung and Endo, either alone or in combination, do not teach or suggest all of

Re: Hung et al
Application No 10/825,752
Filed: 04/16/04
Page 15 of 20

Docket No. 12.023011 CIP

the limitations of claims 2-5. In view of the foregoing, the rejection of claims 2-5 under U.S.C. § 103(a), should be reversed.

Issue 4--Whether claims 1 and 3 are patentable under the doctrine of obviousness-type double patenting in view of claim 26 of U.S. Patent No. 6,391,026.

Claims 1 and 3 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of U.S. Patent No. 6,391,026 to Hung. In the Office Action of August 29, 2006, the Examiner states that “Claim 26 of Hung recites the same method comprising treating a breast duct with vibrational energy. Although the vibrational energy of Hung is used to activate the agent in the duct, the result is still an application of ultrasound to the duct.” (see page 2; second paragraph). The Appellant respectfully disagrees.

Claim 26 of Hung recites a method of treating a breast duct of a patient by the administration of an agent into the breast duct and subsequent delivery of specific energies (such as light, radiation, electromagnetic or vibrational) sufficient to disrupt the agent whereupon the agent is then in a form to act on target cells in a breast duct. There is nothing in Hung that would suggest the use of vibration to increase the retrievable amount of cells collected from a breast duct. Claim 26 of Hung is a method of treatment claim and claim 1 of the present invention is a method of collecting cells. The Appellant disagrees that these claims are not patently distinct. The mere fact that both claims mention the use of vibrational energy is not sufficient to suggest that the claims are similar. In view of the foregoing, the rejection of claims 1 and 3 under the doctrine of obviousness-type double patenting should be reversed.

Conclusion

In view of the arguments presented above, the Appellants contend that each of claims 1-5 are patentable. Therefore, reversal of the rejections under 35 U.S.C. §102(b); 35 U.S.C. §103(a), and under the doctrine of obviousness-type double patenting is respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Theodore R. Allen', is written over a horizontal line.

Theodore R. Allen
Registration No. 41,578
Cytoc Corporation
250 Campus Drive
Marlborough, MA 01752
Tel: 508-263-8490
Fax: 508-263-2959

Customer No, 38732

APPENDIX A: PENDING CLAIMS

1. A method for increasing a retrievable cell amount in a breast duct comprising the steps of:
applying vibration to a breast duct sufficient to induce cell sloughing within said breast duct and;
collecting said sloughed cells from said breast duct;
wherein applying vibration to said breast duct increases the retrievable amount of cells collected from said breast duct.
2. A method as in claim 1, wherein said vibration is produced by ultrasound.
3. A method as in claim 1, wherein said vibration is applied to said breast duct either externally or internally.
4. A method as in claim 1, wherein said vibration is combined with heat and/or massage.
5. A method as in claim 1, wherein said retrievable cell amount is collected through ductal lavage.

APPENDIX B: EVIDENCE

NONE

Re: Hung et al
Application No 10/825,752
Filed: 04/16/04
Page 20 of 20

Docket No. 12.023011 CIP

APPENDIX C: RELATED PROCEEDINGS

NONE